

Areacor Therapeutics

AT278 Phase I delivers better than expected results

20 September 2021

- The [Phase I](#) trial of Areacor's ultra-concentrated ultra-rapid insulin, AT278, has met all primary and secondary endpoints, demonstrating a superior pharmacokinetic (PK) and pharmacodynamic (PD) profile to a comparable dose of lower concentration of NovoRapid (NovoNordisk's gold standard rapid acting insulin).
- The trial evaluated 38 adults with Type I diabetes in an euglycaemic clamp setting comparing AT278 with NovoRapid, with the aim of establishing PK/PD equivalence. A subcutaneous dose of AT278 0.3 U/Kg (500 U/mL) was compared with 0.3 U/Kg NovoRapid (100 U/mL). AT278 matched or exceeded key measures such as glucose lowering, onset of action, and absorption profile, and there were no safety signals.
- The results are impressive as AT278 is an ultra-concentrated rapid acting insulin, which is five-fold (500 U/ml) more concentrated than the NovoRapid comparator. The formulation of a higher concentration rapid-acting insulin is challenging as increases in concentration typically result in notably reduced absorption, slowing the onset of action and shifting the absorption curves of concentrated formulations to the right.
- Such challenges mean there are no high concentration rapid mealtime (prandial) insulins available, with the highest concentration rapid product being [Humalog U-200](#) (lispro, Eli Lilly) at 200 U/ml. The existing 500 U/ml products, such as (Humulin U-500), are slower acting. Thus, these Phase I results position ART278 as a disruptive formulation, opening up the prandial insulin market as the only concentrated rapid-acting insulin.
- In addition, there are a growing number of patients with high daily insulin requirements (>200 units/day), typically Type II and refractory Type I diabetics. AT278's appeal is not simply to reduce the injection burden, but to allow wider access to next-generation miniaturised insulin pumps (where their smaller size often results in limited reservoir capacities). Importantly, algorithm-driven devices require a rapid acting insulin to optimise glycaemic control.

Price	247p
Market Cap	£68.4m
Primary exchange	AIM
Sector	Healthcare
Company Code	AREC
Corporate client	Yes

Company description:

Areacor Therapeutics is a revenue-generating clinical stage drug developer, with a well-balanced portfolio of in-house and partnered programmes. Its proprietary Arestat formulation platforms result in enhanced products with lower development risks and less onerous regulatory approvals.

Trinity Delta view: AT278's Phase I results have demonstrated a better-than-expected absorption profile that positions it as a unique and highly desirable rapid acting ultra-concentrated insulin. Its profile could address unmet needs in both the prandial and high insulin requiring diabetes markets, as well as potentially lowering the barrier to adoption of insulin pumps. Planning is underway to initiate the next clinical study in 2022 to further demonstrate the benefits of AT278. We expect licencing discussions to follow a Phase II study and data package completion (clinical, stability and toxicology). The AT278 results also highlight the strength of Areacor's formulation expertise, confirming its ability to develop novel products with enhanced properties, improved physical characteristics, and better therapeutic profiles. We recently initiated coverage ([September 2021 Initiation](#)) with a £103.7m (374p per share) valuation.

Analysts

Lala Gregorek

lgregorek@trinitydelta.org

+44 (0) 20 3637 5043

Franc Gregori

fgregori@trinitydelta.org

+44 (0) 20 3637 5041

Lala Gregorek

lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Franc Gregori

fgregori@trinitydelta.org
+44 (0) 20 3637 5041

Disclaimer

Trinity Delta Research Limited ("TDRL"; firm reference number: 725161), which trades as Trinity Delta, is an appointed representative of Equity Development Limited ("ED"). The contents of this report, which has been prepared by and is the sole responsibility of TDRL, have been reviewed, but not independently verified, by ED which is authorised and regulated by the FCA, and whose reference number is 185325.

ED is acting for TDRL and not for any other person and will not be responsible for providing the protections provided to clients of TDRL nor for advising any other person in connection with the contents of this report and, except to the extent required by applicable law, including the rules of the FCA, owes no duty of care to any other such person. No reliance may be placed on ED for advice or recommendations with respect to the contents of this report and, to the extent it may do so under applicable law, ED makes no representation or warranty to the persons reading this report with regards to the information contained in it.

In the preparation of this report TDRL has used publicly available sources and taken reasonable efforts to ensure that the facts stated herein are clear, fair and not misleading, but make no guarantee or warranty as to the accuracy or completeness of the information or opinions contained herein, nor to provide updates should fresh information become available or opinions change.

Any person who is not a relevant person under section of Section 21(2) of the Financial Services & Markets Act 2000 of the United Kingdom should not act or rely on this document or any of its contents. Research on its client companies produced by TDRL is normally commissioned and paid for by those companies themselves ('issuer financed research') and as such is not deemed to be independent, as defined by the FCA, but is 'objective' in that the authors are stating their own opinions. The report should be considered a marketing communication for purposes of the FCA rules. It has not been prepared in accordance with legal requirements designed to promote the independence of investment research and it is not subject to any prohibition on dealing ahead of the dissemination of investment research. TDRL does not hold any positions in any of the companies mentioned in the report, although directors, employees or consultants of TDRL may hold positions in the companies mentioned. TDRL does impose restrictions on personal dealings. TDRL might also provide services to companies mentioned or solicit business from them.

This report is being provided to relevant persons to provide background information about the subject matter of the note. This document does not constitute, nor form part of, and should not be construed as, any offer for sale or purchase of (or solicitation of, or invitation to make any offer to buy or sell) any Securities (which may rise and fall in value). Nor shall it, or any part of it, form the basis of, or be relied on in connection with, any contract or commitment whatsoever. The information that we provide is not intended to be, and should not in any manner whatsoever be, construed as personalised advice. Self-certification by investors can be completed free of charge at www.fisma.org. TDRL, its affiliates, officers, directors and employees, and ED will not be liable for any loss or damage arising from any use of this document, to the maximum extent that the law permits.

Copyright 2021 Trinity Delta Research Limited. All rights reserved.

More information is available on our website: www.trinitydelta.org